DEPARTMENT OF HEALTH & HUMAN SERVICES

9/8/8d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-03

October 11, 2001

Phat T. Lam, President
China Farms, Inc.
3717 North Schofield
Indianapolis, IN 46218

Dear Mr. Lam:

On May 18th & 23rd, 2001, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 3717 North Schofield, Indianapolis, Indiana. The inspection was conducted to determine compliance with the current Good Manufacturing Practice requirements (cGMP's) for foods (21 CFR 110), The Federal Food, Drug and Cosmetic Act (hereafter referred to as "The Act") and to determine if your mung bean sprout processing operations were conducted under sanitary conditions.

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the cGMP's for foods (21 CFR 110). The FDA investigator presented your firm with a list of inspectional observations (FDA-483) which presents the investigator's evaluation of your firm's performance regarding various aspects of the current Good Manufacturing Practice requirements for foods (21 CFR 110).

During the inspection, it was determined that your firm failed to take appropriate corrective action when a spent irrigation water sample tested positive for *Salmonella*. In addition, your firm had inadequate seed disinfection.

As such, these sprout products are adulterated within the meaning of 402(a)(4) of the Act because they are being produced under insanitary conditions that may render sprouts injurious to health. The conditions under which these sprouts products are being produced are considered unsanitary since effective preventive controls, particularly appropriate corrective action when spent irrigation water sample tested positive for *Salmonella* and inadequate seed disinfection, have not been adopted and implemented by your sprouting facility.

The above is not intended to be an all inclusive list of deviations at your facility. It is your responsibility to assure that your establishment is in full compliance with all requirements of the federal regulations.

You should take prompt measures to correct this deviation. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct this violation, including an explanation of each step taken to prevent its recurrence. If corrections cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your written reply should be directed to Ms. Greta L. Budweg, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson Ave., Detroit, MI 48207.

Sincerely yours,

Joann M. Givens
District Director
Detroit District